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SCIENTIFIC DATA REVIEWS  
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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: MYCLOBUTANIL- Report of the Risk Assessment Review Committee

FROM: Jess Rowland, Executive Secretary *Jess Rowland 11/29/97*  
Risk Assessment Review Committee,  
Health Effects Division (7509C)

THROUGH: Karen Whitby, Chair *KW 11/25/97*  
Risk Assessment Review Committee  
Health Effects Division (7509C)

TO: Melba Morrow, Branch Senior Scientist  
Registration Action Branch 1  
Health Effects Division (7509C)

and

Luis Suguiyama, Chief  
Fungicide Branch  
Registration Division (7505C)

PC Code: 128857

The Health Effects Division (HED) Risk Assessment Review Committee (RARC) met on November 19, 1997 to review the risk assessment document that evaluated the Registrant's request for the establishment of a Permanent Tolerance for the combined residues of **Myclobutanil on bananas (PP # 2E04141)**. The Committee's recommendations and conclusions are attached.

The Health Effects Division (HED) Risk Assessment Review Committee (RARC) met on November 19, 1997 to review the risk assessment document that evaluated the Registrant's request for the establishment of a Permanent Tolerance for **Myclobutanil** on bananas (PP # 2E04141). The Committee's conclusions and recommendations are as follows:

<u>Page No.</u>	<u>Recommendations</u>
26	<i>Section 2.c.ii. Dermal Absorption:</i> # 2. revise as follows " a dermal absorption factor could not be estimated due to the lack of comparative NOELs/LOELs from oral and developmental studies on the technical compound. Also, the last sentence, correct "21"-day to a 28-day dermal toxicity study.
27	<i>Section 2.c.iii. Intermediate Term Occupational/Residential Exposure.</i> Revise Developmental NOEL/LOEL to Reproductive NOEL/LOEL. The effect (pup weight decrements) come under the "Reproductive NOEL/LOEL.
29	(iii). Revise as follows: This dose should then be compared to the oral NOELs of 10 mg/kg/day for Intermediate-Term exposure and 2.49 mg/kg/day for Long-Term Exposure to calculate Margins of Exposure.
30/32	<i>Section 3.a.ii. Plant Metabolism:</i> Translate the plant metabolism data from Apples and Grapes to Bananas (i.e., nature of the residues in bananas may be similar to that seen in the other fruits (apples and grapes).
57	<i>Surface Water- EEC -GENEC:</i> Note: change "EPA" policy to HED policy.
57/58	<i>Section c.i. Chronic Risk (ARC):</i> The following statement on Page 57 "With the exception of bananas, all commodities having Myclobutanil tolerances will contain Myclobutanil and metabolite residue and those residues will be at the level of established tolerance" .....conflicts with the following statement on Page 58 "Percent crop-treated estimates were utilized for selected commodities included in the assessment". Revise appropriately.
58	<i>iv. Drinking Water Risk:</i> Discussion of drinking water risk should be presented in a qualitative manner - consult S.Knizner for assistance
59	<i>4. Occupational and Residential Exposure:</i> Based on the use pattern, residential exposure risk assessment is required. HED's surrogate data should be used for this exposure and risk assessment. Check files and consult with EXPO.SAC.
61	<i>Section .c. Determination of Safety for Infants and Children:</i> Revise the last sentence as follows: Therefore, the Agency concluded that the additional 10 x factor to account for enhanced sensitivity to infants and children is not required and that an Uncertainty Factor of 100 is adequate to ensure the safety of this population (i.e, infants and children) from dietary exposure to Myclobutanil
61	<i>Section d. ii Chronic Aggregate Exposure.....Children:</i> This section needs to be revised since per current HED policy, dietary drinking water risk can be estimated only for adult males, adult females and children (1-6 years). Therefore, only these population sub-groups can be carried forth in this assessment.



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**Chemical:** Myclobutanil

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